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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WANG, CHANG YU	

ART UNIT	PAPER NUMBER
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,115	TAKAYAMA ET AL.	
	Examiner	Art Unit	
	Chang-Yu Wang	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RESPONSE TO AMENDMENT

Status of Application/Amendments/claims

1. Applicant's amendment filed 4/14/08 is acknowledged. Claims 1-12 are cancelled. Claims 13-16 are amended. Claims 17-22 are newly added. Claims 13-16 and newly added claims 17-22 are pending in this application and under examination in this office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response.

3. Applicant's arguments filed on 4/14/08 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Specification

4. The objection to the specification is withdrawn in response to Applicant's amendment to the title and the specification.

Claim Rejections/Objections Withdrawn

5. The objection to claims 13-16 is withdrawn in response to Applicant's amendment to the claims.

The rejection of claims 13-16 under 35 U.S.C. 112, first paragraph, because the specification does not enable the invention commensurate in scope with the claims is withdrawn in response to Applicant's amendment to the claims and arguments.

Claim Rejections/Objections Maintained

In view of the amendment filed on 4/14/08, the following rejections are maintained.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

At p. 8-9 of the response, Applicant argues that the rejection is overcome because amended claims have been limited to SSTR2 and SSTR4 and the specification provides examples for the somatostatin receptor agonists usable in the claimed method and the agonists can also be confirmed by a screening method known in the art. Applicant further argues that WO98/44922 and WO97/43278 teach methods of screening for somatostatin receptor agonists. Applicant's arguments have been fully considered but they are not persuasive.

In contrast to Applicant's arguments, the specification only teaches somatostatin, t-butyl 6-amino-2-(3-(lH-indol-3-yl)-2-((4-(2-oxo- 2,3-dihydrobenzoimidazol-l-yl)piperidine-l- carbonyl)amino)propionylamino)hexanoate (compound 1), and l-(3-(N-(5-bromopyridin-2-yl)-N-(3,4-dichlorobenzyl)amino)propyl)-3-(3-(1H-imidazol-4-

yl)propyl)thiourea (compound 2) that can be used in the claimed methods. However, the claims 13-17 are not limited to the agents as set forth above. The specification fails to describe what common structures, amino acid sequences and characteristics are required the SSTR2 and SSTR4 agonists that can be used in the claimed method. The structural and functional relationship of the claimed genus of SSTR2 and SSTR4 agonists are unknown. Thus, a skilled artisan cannot envision the structural and functional correlation of the claimed genus with the claimed method. Note that

A definition by function alone "does not suffice" to sufficiently describe a coding sequence "because it is only an indication of what the gene does, rather than what it is." *Eli Lilly*, 119 F.3 at 1568, 43 USPQ2d at 1406. See also *Fiers*, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing *Amgen Inc. v.Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991)). An adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., *Univ. of Rochester v. G.D. Searle &Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004).

Accordingly, the court held in *Univ. California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997) that:

"One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is".

In this case, in contrast, the specification provides an invitation for others to discover a representative number of species, or to discover what constitutes any particular portion of the structure that must be conserved, with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics. Thus, Applicant was not reasonably in possession of the "claimed genus of SSTR2 and SSTR4 agonists" that can be used in the claimed method. See MPEP 2163.

Accordingly, the rejection of claims 13-17 under 35 U.S.C. §112, first paragraph, as failing to meet the written description requirement is maintained.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-22 are rejected under 35 U.S.C. 102 (b) as being anticipated by Nordisk (WO98/58646, published on Dec 30, 1998 as in IDS).

At p. 10 of the response, Applicant argues that although WO98/58646 teaches treatment of different eye diseases, no pharmacological data supportive of the use of agonists for the recited diseases. Applicant's arguments have been fully considered but they are not persuasive.

In contrast, based on MPEP, an actual working example is not required for compliance with the enablement requirement of 35 U.S.C. 112, first paragraph.

"An example may be 'working' or 'prophetic.' A working example is based on work actually performed. A prophetic example describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved."

and also In *in re Borkowski*, the court held that

"The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970). See MPEP § 2164.02.

At p. 10 of the response, Applicant argues that WO98/58646 does not teach a method of promoting extension of corneal nerve axon, recovering the sensitivity of decreased corneal sensitivity with corneal nerve damage, a method of treating dry eye associated with decrease of corneal sensitivity and a method of treating corneal epithelium defect associated with decrease of corneal sensitivity. Applicant's arguments have been fully considered but they are not persuasive.

In contrast, WO98/58646 does teach the claimed methods. The limitations of "promoting extension of corneal nerve axon, recovering the sensitivity of decreased corneal sensitivity with corneal nerve damage, treating dry eye associated with decrease of corneal sensitivity and treating corneal epithelium defect associated with decrease of corneal sensitivity" are the intended results of administration of somatostatin or SSTR2 or SSTR4 agonists to a patient with eye diseases caused by corneal nerve damage or caused by a corneal epithelium defect associated with decrease of corneal sensitivity. Note that claim preamble language may not be treated as a limitation where it merely states an intended use of the system and is unnecessary to define the invention, the U.S. Court of Appeals for the Federal Circuit ruled May 8 (Catalina Marketing Int'l Inc. v. Coolsavings. com Inc., Fed. Cir., No. 01-1324, 5/8/02). In this case, the patient, the active step and the material in the claimed method as recited in the body of the claims are disclosed by WO98/58646; thus, the claimed inventions with the intended results as described above can be achieved in the patients having the eye disease caused by corneal nerve damage or caused by a corneal epithelium defect, and treated with somatostatin or SSTR2 or SSTR4 agonists, which is taught by

WO98/58646. The intended results as recited in the claims also occur in patients having the eye disease such as glaucoma, inflammation of corneal stroma, stromal keratitis, iritis, retinitis, cataract and conjunctivitis and treated with somatostatin because these different eye diseases also affect corneal epithelium or cause corneal nerve damage or dry eye and corneal sensitivity as evidenced by Suzuki et al and Fini et al. (see p. S12 2nd col., Fini et al. Arch Dermatol. Res. 1998. 290: S12-S23). Note that

"If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction. *Pitney Bowes, Inc.v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir.1999). See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir.1997) ('where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation'); *Kropa v. Robie*, 187 F.2d at 152, 88 USPQ2d at 480-81 (preamble is not a limitation where claim is directed to a product and the preamble merely recites a property inherent in an old product defined by the remainder of the claim)." See MPEP § 2111.02 [R-3]

At p. 10 of the response, Applicant argues that although WO98/58646 teaches treatment of different diseases of cornea, stroma and epithelium including glaucoma, stroma keratitis, iritis, retinitins, cataract and conjunctivitis with certain somatostatin receptor agonists, WO98/58646 is aiming at treatment of inflammatory diseases but the instant invention is aiming at treating the claimed diseases by promoting extension of corneal nerve axon in the cornea with damaged corneal nerves. Applicant's arguments have been fully considered but they are not persuasive.

In response, regardless of what mechanisms underlying somatostatin action, as long as the prior art teaches the same patient population, the same material, and the same active step as recited in the claimed method, the prior art anticipates the claimed invention. In this case, for the reasons set forth above, WO98/58646 teaches

administration of somatostatin to patients having different eye diseases that affect corneal epithelium or cause corneal nerve damage or dry eye and corneal sensitivity, which have the same patient population, same material and same active step. Thus, WO98/58646 anticipates that claimed method regardless of what mechanisms underlying somatostatin action in treatment of these different diseases. Note that

"The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342,1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). " See MPEP § 2112.01 [R-3].

At p. 10 of the response, Applicant further argues that WO98/58646 does not teach the topical administration route to the eye of the instant invention. Applicant's arguments have been fully considered but they are not persuasive.

In contrast, WO98/58646 does teach topically administration of somatostatin to patient having the claimed diseases because WO98/58646 teaches pharmaceutical compositions comprising somatostatin for topical application (see p. 30, lines 16-20 and p.33). As explained above, the diseases taught by WO98/58646 also affect corneal epithelium or cause corneal nerve damage or dry eye and corneal sensitivity. Thus, any administration route to effectively act on the desired site would include administration of somatostatin to eyes; and somatostatin for topical application is for the purpose of topical administration to the desired site, which would be the affected eyes.

Conclusion

8. NO CLAIM IS ALLOWED.

9. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday from 8:30 AM to 6:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached at (571) 272-0911.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/CYW/
Chang-Yu Wang, Ph.D.
July 8, 2008

/Christine J Saoud/
Primary Examiner, Art Unit 1647